PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Title:	METHOD FOR THE DEVELOPMENT OF AN HIV VACCINE
Appl. No.:	10/667,534
Applicant:	Adan Rios
Filed:	09/22/2003
Art Unit:	1648
Examiner:	Parkin, Jeffrey S.
Docket No.:	RIOS:004USC2
Customer No.:	32425
Confirmation No.	9949

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June 17, 2008 — Travis M. Wohlers
Date

REPLY BRIEF

MAIL STOP APPEAL BRIEF - PATENTS
Commissioner for Patents
P. O. Box 1450
Alexandria, VA 22313-1450

Dear Sir:

Appellant submits this Reply Brief to the Board of Patent Appeals and Interferences in response to the Examiner's Answer dated April 17, 2008. The deadline for filing the Reply Brief is June 17, 2008. It is believed that no fee is due in connection with the filing of this paper; however, should any fees under 37 C.F.R. §§ 1.16 to 1.21 be required for any reason relating to the enclosed material, the Commissioner is authorized to deduct or credit said fees from or to Fulbright & Jaworski L.L.P. Account No.: 50-1212/RIOS:004USC2.

REPLY TO THE EXAMINER'S ANSWER

A. The examiner is improperly trying to limit the claims to a preferred embodiment.

It is well established that is improper to limit a patent's claims to a preferred embodiment disclosed in the specification. See e.g., *Liebel-Flarsheim Co. v. Medrad Inc.*, 358 F.3d 898, 906, 69 USPQ2d 1801, 1807 (Fed. Cir. 2004) ("this court has expressly rejected the contention that if a patent describes only a single embodiment, the claims of the patent must be construed as being limited to that embodiment."). Nevertheless, this is precisely what the examiner is attempting to do with the written description rejection that is the subject of this appeal. The Examiner's Answer asserts that the Appellant was "clearly focused on HIV-1." To support this assertion, the examiner cites, at length, passages from the specification in which HIV is discussed.

Appellant acknowledges that HIV was used to exemplify the teachings in the specification. The specification, however, clearly discloses that its teachings are applicable to any viral particle comprising a reverse transcriptase. In particular, the specification teaches that "the methodology of the present invention is ***applicable to any retrovirus*** which may be associated with any animal or human disease as a method for development of effective immunogens and preventative vaccines. ***Thus, the present invention has a broader applicability than the exemplified HIV vaccine.***" (p. 16, ln. 20-23).

Regardless of whether the examiner believes that Appellant was "clearly focused on HIV-1" or that HIV was used to exemplify the teachings in the specification, this simply does not provide a basis for a written description rejection; particularly in view of the specification's express statements of broader applicability. The examiner is, therefore, improperly attempting to limit Appellant's claims to a preferred embodiment.

B. A patent need not teach what is well known in the art.

The examiner argues that although the specification states that present invention is applicable to any retrovirus, nothing in the specification would lead the skilled artisan to any particular retrovirus. *Examiner's Answer*, p. 9. The examiner, however, fails to establish that the skilled artisan requires any "leading" in this regard.

As explained in the specification, all retroviruses possess a reverse transcriptase (RT) enzyme, which converts the RNA of their genetic material into DNA (Specification, p. 3, ln. 14-16). Since retroviruses cannot integrate into the genetic machinery of the host cell without reverse transcription, the inhibition of reverse transcriptase has as a universal consequence on the inability of any retrovirus to integrate within the genetic machinery of a suitable host cell. The importance of RT to retroviruses, is further evidenced by the number of known anti-retroviral compounds that interfere with RT activity (e.g., AZT, nevirapine, pyridinones, carboxanilides) (Specification, p. 3, ln. 23 to p. 4, ln. 8). Thus, the inactivation of reverse transcriptase as described in the present specification would be understood by a person of ordinary skill in the art to be applicable to retroviruses in general.

"[A] patent need not teach, and preferably omits, what is well known in the art." *Hybridtech Inc. v. Monoclonal Antibodies, Inc.*, 802 F.2d 1367 (Fed. Cir. 1987). Accordingly, Appellant's specification need not provide a detailed description of all viruses having a reverse transcriptase because such are well known to those in the art. For example, HIV, human T-cell lymphotropic virus (HTLV-1), murine leukemia virus, and feline leukemia virus are well-known, pathogenic retroviruses. Knowledge of reverse transcriptases and retroviruses by those in the art is evident from the publications provided in the Evidence Appendix of Appellant's Appeal Brief.

The Federal Circuit's recent decision in *Falkner v. Inglis* is illustrative in this regard. In *Falkner*, the court upheld the Board's conclusion that Inglis's priority applications provided

adequate written description of "a vaccine" comprising a mutant poxvirus having an inactivating mutation in an essential gene even though (1) the Inglis applications did not identify any essential genes in poxvirus or describe the inactivation of such genes, (2) no vaccines based on poxvirus had yet been produced by Inglis, and (3) the bulk of the Inglis specification was directed to herpesvirus rather than poxvirus. *Falkner v. Inglis*, 448 F.3d 1357, 1362 (Fed. Cir. 2006). In reaching this decision, the court noted that the Inglis applications described ***"vaccine vectors in general"*** and that the ***"invention can be applied to any virus where one or more essential gene(s) can be identified and deleted from or inactivated within the virus genome."*** *Id.* at 1364.

The court further stated that "there is no per se rule that an adequate written description of an invention that involves a biological macromolecule must contain a recitation of known structure." *Id.* at 1366. Further, the court found that essential genes for poxvirus were well known in the art. *Id.* Accordingly, the court held that because accessible literature sources provided the "essential genes" to be in activated in a poxvirus as of the relevant date, the Inglis applications provided adequate written description of the claimed vaccine. *Id.* at 1368.

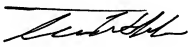
Thus, like in *Falkner* where the court determined that the invention could be applied to any virus where one or more essential genes could be identified and deleted, a person of ordinary skill in the art would understand that the currently claimed invention can be applied to any viral particle comprising a reverse transcriptase because the specification teaches that the reverse transcriptase can be inactivated by binding the reverse transcriptase with one or more azido-labeled compounds and then irradiating the reverse transcriptase. The viral particle with the inactivated reverse transcriptase could then be administered to a subject to elicit an immune response.

In view of the above, the present specification describes the claimed invention in sufficient detail that one of ordinary skill in the art can reasonably conclude that Appellant had possession of the claimed invention at the time of filing.

C. The Examiner's Answer failed to address the separate patentability of claims 43-47.

Appellant separately argued dependent claims 43-47 in the Appeal Brief. The Examiner's Answer failed to address these arguments. Moreover, the examiner also failed to explain why the specification did not provide adequate written description for claims 43-47 in the final Office Action. In fact, he indicated that the subject matter of these claims was supported by adequate written description. Accordingly, the rejection of claims 43-47 should be overturned.

Respectfully submitted,



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